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Optical Coherence Tomography comparison of Trapidil versus Paclitaxel Eluting Stent Implanted in non ST Elevation Myocardial Infarction

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Background: Percutaneous coronary intervention (PCI) with DES is a well established treatment in patients with non ST elevation myocardial infarction (NSTEMI), but up to 25% of patients need repeat target lesion revascularization due to restenosis or thrombosis. These events seem to be related with delayed re-endothelialization and malapposition of stent struts

Aim of the study: To evaluate 45 days strut coverage and malapposition by optical coherence tomography (OCT) between 1st generation Paclitaxel eluting stent (TAXUSTM) and 2nd generation Trapidil eluting stent (INTREPIDTM) implanted in NSTEMI.

Methods: Pts with symptoms of NSTEMI (defined by the ACC/AHA criteria), with two discrete angiographic lesions in different coronaries, one to be treated during index procedure, the second amenable of planned PCI 45 days thereafter. Patient randomly received TAXUSTM or INTREPIDTM stent during index procedure, and after 45 days the other stent in a crossover design. OCT evaluation of the stent implanted during index procedure was performed at the time of the second procedure.

Results: Twenty-one patients were enrolled, 11 in the Intrepide and 10 in the Taxus arm. Mean age was 69.3±8.2 yo. 84.2% were male, 15.8% diabetics, 47.4% hypercholesterolemic. Treated vessel was LAD in 15.78%, LCX in 63.1% and RCA in 21.05% of cases. Lesion length was 24.2±10.8 mm; RVD was 3.2 ± 0.3 mm; number of stent implanted per lesion was 1.18. OCT follow up was performed in 14 patients, 6 in the Taxus group, 8 in the Intrepide group. Neointimal growth and malapposition were analyzed at each stent strut of cross-sectional OCT images with 0.5-mm intervals. Mean neointimal thickness was 196.7±80 µm in the Taxus group vs 317.1±131 µm in the Intrepide group (p<0.001). Percentage of neointima hyperplasia was 14.7±6. in the Taxus group vs. 38.6±12 in the Intrepide group (p<0.001) Percentage of uncovered and malapposed stent struts was 11.79% and 2.07% of total struts analyzed in the Taxus group vs 0.4% and 0% of total struts analyzed in the Intrepide group, respectively. Frames with RUTTS> 30% was 18% in the Taxus group vs 0.7% in the Intrepide group.

Conclusions: The Intrepide stent shows complete early coverage compared to 1st generation DES. However neointimal formation is significantly greater in the early period and this could translate to angiographic restenosis in the long-term follow-up.

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Vulnerable Neointimal Tissue Evaluation Using Integrated Backscatter Intravascular Ultrasound In the Treatment Of Drug-eluting Stent Restenosis

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Background: Pathologic studies have suggested that tissue characteristics of neointima after drug-eluting stent (DES) were different from those of bare-metal stent. Integrated backscatter intravascular ultrasound (IB-IVUS) has enabled in-vivo tissue characterization of coronary plaque. In this study, we investigated online tissue characterization of neointima at the site of target lesion revascularization (TLR) before treatment of DES restenosis.

Method: We performed 6-8 months follow-up coronary angiography (CAG) in 140 DES implanted lesions. TLR rate was 15.6% (15/96) in sirolimus-eluting stents (SES) and 15.9% (7/44) in paclitaxel-eluting stents (PES), respectively. Before treatment, quantitative gray scale IVUS analysis was performed. Tissue characteristics in stented segments (10mm length including minimal lumen area) were also analyzed using IB-IVUS. Neointimal tissue components of each slice were divided by four categories (category 1: calcific (-29 to -11dB), category 2: dense fibrotic (-35 to -29dB), category 3: fibrotic (-49 to -35dB), and category 4: lipidic (-130 to -49dB)).

Results: After treatment of DES restenosis, distal embolization had occurred in 6 lesions (3 SES and 3 PES). When compared neointimal tissue components in restenotic segments with (group D, n=6) and without distal embolization (group N, n=11), there were no significant differences of stent size, stent length, and neointimal area between groups. However, IB-IVUS data revealed that category 3 (fibrotic component) was significantly smaller in group D (62 ± 6%) than group N (70 ± 6%) (p=0.04) and category 4 (lipidic component) was significantly larger in group D (33 ± 6%) than group N (21 ± 8%) (p<0.01). Furthermore, compared with group N, group D had heterogeneous neointimal tissue characteristics throughout the stent.

Conclusion: In the treatment of DES restenosis, vulnerable neointima existed in some cases. IB-IVUS may enable in-vivo tissue characterization of neointima in DES restenosis.

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Intimal Thickening Of Non-Atheromatic Coronary Segments is Associated with Thin Cap Fibroatheroma in Patients with Acute Coronary Syndromes

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Background: Intimal thickening is implicated in the pathogenesis of the early stages of atheromatosis. Optical coherence tomography (OCT) imaging allows for precise measurements of intimal thickness of non-atheromatic coronary segments. Yet, the significance of such measurements has not been investigated so far. We aimed to investigate in patients with acute coronary syndromes (ACS) the association of intimal thickness in non-atheromatic proximal segments of the culprit lesions (CLs) with thin cap fibroatheroma (TCFA) and rupture of the CL.

Methods: Fifty five consecutive patients with ACS that underwent cardiac catheterization within 24 hours from symptom onset were enrolled. Optical coherence tomography study was then performed in all CLs. Images from proximal segments and from the CL were stored and analysed offline. Maximum intimal thickness was measured at proximal sites where the vessel wall had a three-layered appearance, without eccentric thickening (as defined by a ratio of maximum intimal thickness/minimum intimal thickness>3). Patients that did not present such morphology (i.e. patients with atheromatic healthy segments) were excluded from the study. Presence of culprit plaque rupture was recorded and fibrous cap thickness was measured at the thinnest part of the plaque of CLs. TCFA was defined as a plaque with cap thickness <65µm.

Results: Images were successfully acquired from all 55 patients. In twelve patients no proximal non-atheromatic segment was identified, and were excluded from the study. Analysis of the remaining 43 patients revealed that mean intimal thickness of proximal segments in all patients was 259±86

um. Twenty seven patients (62.8%) had at least one TCFA at the CL. Mean intimal thickness of the proximal segments in patients with TCFA was greater than that of patients without TCFA (290±81 um vs 206±69 um, p=0.01). Sixty five percent of the plaques (n=28) were ruptured. No significant difference was found in the intimal thickness of proximal healthy segments between patients with or without plaque rupture (268±93 um vs. 247±78 um, p=NS).

Conclusion: In patients with ACS, increased intimal thickness of non-atheromatic proximal segments of plaques is associated with TCFA, but not with plaque rupture. Our findings suggest that atherosclerotic changes of the vessel wall are associated with culprit plaque morphology in acute coronary syndromes.

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Intravascular Ultrasound-guided Coronary Artery Interventions with Drug-eluting Stents in Coronary Bifurcation Lesions in Asian Population

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Backgrounds: There are limited data regarding efficacy of intravascular ultrasound (IVUS)-guided percutaneous coronary interventions (PCI) with drug-eluting stents (DES) focused on coronary artery bifurcation lesions in real world clinical setting.

Methods: A total 664 consecutive patients (pts) with bifurcated coronary artery stenosis (including left main lesions) who underwent PCI with DESs were enrolled. The IVUS usage was depend on physician's discretion. The study populations were divided into no IVUS group (n= 517 pts) and IVUS group (n= 147 pts). The 6-month angiographic and 1-year clinical outcomes were compared between the two groups.

Results: Baseline clinical characteristics were similar between the two groups except more dyslipidemia (20.7% vs. 14.3%, p=0.09), less left main (8.7% vs. 33.3%, p<0.001) and ostial (38.5% vs. 63.3%,p=0.001) lesions in no IVUS group. Angiographic outcomes at 6-month and the incidence of Q wave myocardial infarction, repeat PCI and major adverse cardiac events (MACEs) were similar between the two groups up to 1 year. However, there was a trend towards higher 1-year total mortality in no IVUS group compared with that of IVUS group (Table).

Table. Six-month angiographic and twelve-month clinical outcomes between no IVUS and IVUS group.

	No IVUS Group (n=517 pts)	IVUS Group (n=147 pts)	P
Six-month angiographic outcomes			
Follow Up MLD	2.32 ± 0.74	2.46 ± 0.85	0.540
Diameter restenosis (%)	24.01 ± 20.98	23.39 ± 20.88	0.390
Late loss	0.55 ± 0.69	0.62 ± 0.72	0.098
Binary restenosis	34 (12.0)	12 (15.0)	0.243
One-year clinical outcomes			
Total Death	24 (4.6)	2 (1.4)	0.057
Cardiac death	14 (2.7)	1 (0.7)	0.125
Q-wave MI	4 (0.8)	3 (2.0)	0.414
TLR	42 (8.1)	16 (10.9)	0.365
TVR	48 (9.3)	17 (11.6)	0.492
TLR-MACEs	56 (10.8)	16 (10.9)	0.910
TVR-MACEs	72 (13.9)	19 (12.9)	0.714
All MACEs	85 (16.4)	23 (15.6)	0.830

Conclusion: IVUS guided coronary artery interventions with DES in coronary bifurcation lesions were failed to show the major benefits in terms of 6-month angiographic and 12-month clinical outcomes in a series of Asian population.

Key word: Intravascular ultrasound, percutaneous coronary intervention,

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Intracoronary Laser Speckle Imaging: a Novel Optical Technique to Detect Unstable Atherosclerotic Plaque

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Introduction: The detection of unstable coronary plaques is of paramount importance in reducing mortality due acute coronary syndromes. Compelling evidence suggests that mechanical factors play a key role in determining plaque stability. We have developed a new optical tool, Laser Speckle Imaging (LSI), that measures the ensemble Brownian motions of intrinsic light scatterers to evaluate an index of plaque viscoelasticity. In the current abstract we describe the development of the LSI technology for coronary evaluation and present the first demonstration of *in vivo* intracoronary LSI conducted in coronary arteries of living swine.

Methods: We have constructed a portable console and prototype intracoronary catheter (~4.5 F) to conduct *in vivo* LSI. The console consists of a Helium Neon (632nm) source and a high speed CMOS camera capable of conducting LSI at ~1kHz frame rate. The LSI catheter (~4.5 F) consists of an optical fiber to illuminate the arterial wall and an optical fiber bundle to collect arterial speckle patterns via distal micro-optical components. The LSI technology is tested using a human to swine coronary xenograft model in which cadaveric human coronary arteries are excised and grafted on to the beating heart of living swine. Coronary circulation is directed through the graft to confirm physiological blood flow and cardiac motion conditions. LSI is conducted at multiple sites in each artery in conjunction with saline flushing. Time-varying speckle patterns are evaluated using cross-correlation techniques and the speckle decorrelation time constant, τ , which defines an index of plaque viscoelasticity is calculated at each site. *In vivo* LSI measurements of τ are related with *ex vivo* measurements and Histopathological diagnosis of plaque type on sacrifice.

Results and Conclusions: *In vivo* LSI measurements of τ were highly correlated with *ex vivo* measurements at the same coronary sites ($R = 0.93$, $p < 0.01$). Under *in vivo* conditions, LSI measured highly significant differences in τ between the necrotic core fibroatheroma, pathological intimal thickening and fibrous plaques, demonstrating that LSI can discriminate human coronary disease *in vivo* ($p < 0.0001$) under physiological conditions. These studies have shown for the first time that intracoronary LSI can be conducted to evaluate human coronary atherosclerosis *in vivo*. Based on its ability to measure a key mechanical metric related to plaque stability and its suitability for *in vivo* use, we anticipate that LSI will provide a powerful tool to detect unstable coronary plaques in patients

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